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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JOHNSEN, JASON H	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/760,647	SAS ET AL.	
	Examiner	Art Unit	
	Jason H. Johnsen	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

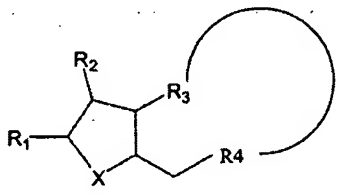
Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06/30/2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Schramm et al. (US 6,121,296). Claim 1 is drawn to a compound of the formula 

, wherein R_1 is selected from the group consisting of alkyl, aryl, O-aryl, S-aryl, OH, O-alkyl, SH, S-alkyl, NH_2, N_3, halogens, -OOCH, and COOH; R_2 is selected from the group consisting of H, hydroxyl, aliphatic and aromatic ethers and esters; R_3 is selected from the group consisting of alkyl, aryl, O-aryl, S-aryl, OH, O-alkyl, SH, S-alkyl, NH_2, N_3, halogens, -OOCH, and COOH, and acetal rings; R_4 is selected from the group consisting of alkyl, aryl, O-aryl, S-aryl, OH, O-alkyl, SH, S-alkyl, NH_2, N_3, halogens, -OOCH, and COOH, and acetal rings; X is selected from the group consisting of O, N, and S. Claim 2 further limits the compound of claim 1, wherein R_1 is preferably phenyl; R_2 is preferably selected from the group consisting of –OMe, -OH, and –H;

R_3 is preferably selected from the group consisting of –OH, -OAc, -OBn, and –H; R_4 is preferably selected from the group consisting of –H, -Oac, and –OBn, or a pharmaceutically active derivative thereof.

Schramm et al. teach a compound of the formula found in claim 1, wherein X is O or N, R_1 is phenyl, and R_2, R_3, and R_4 is each independently hydroxyl (page 11, compound 1, column 47, Table VI).

2. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Matulic-Adamic et al. (US 6,121,296). The limitations of claims 1 and 2 are discussed above. Matulic-Adamic et al. teach a compound of the formula found in claim 1, wherein X is O, R_1 is phenyl, and R_2, R_3, and R_4 is each independently hydroxyl (page 27, compound 5).

3. Claims 1 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Takatsuki et al. (US 5,098,927). Claim 5 is drawn to a method of treating a viral infection in a mammalian subject comprising the step of administering to the subject a composition comprising at least one compound of claim 1 (see column 2). Claim 6 further limits the method of claim 5, wherein the composition contains a compound of claim 1 in an effective anti-viral amount. Claim 7 further limits the method of claim 5 wherein the mammalian subject is a human patient or another mammal.

Takatsuki et al. teach a method of treating a viral infection in a human patient by administering a composition comprising a compound of the formula found in claim 1 (see abstract).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling a method for treating some types of viruses, does not reasonably provide enablement for all types of viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims without undue experimentation.

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." In re Wands, 858 F.2d at 737, 8 USPQ 2d at 1404. These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims are extremely broad due to the fact that there are many types of viruses, all of which are encompassed by the claims. Claim 5-7 are drawn to

methods of treating all viruses by administering compounds of claims 1-4. Applicant has not provided sufficient evidence to support a claim drawn to all viruses.

The nature of the invention

Claim 5 is drawn to methods of treating all viruses by administering compounds of claims 1-3. This is extremely broad and would read on various types of cancers including HIV and HSV

The state of the prior art

In the specification, on page 1, Applicant indicates that CMV is a member of the herpesvirus group, which includes herpes simplex virus types 1 and 2, viricella-zoster virus, and Epstein-Barr virus. Infections CMV may be shed in the bodily fluids of any previously infected person, and thus may be found in the urine, saliva, blood, tears, semen and breast milk. The prior art does not indicate that the instant compound is useful in treating all viruses. In fact, in the applicant's specification on page 21, line 9, applicant states that "no relevant activity was observed against HIV or HSV. Compound A9 showed a slight activity against VV." On page 25 of the specification the applicant notes that the compounds of the instant application possessed highly selective antiviral activity, mainly against CMV.

The level of one of ordinary skill

The level of skill in the art is high, that of a M.D. or PhD.

The level of predictability in the art

The instant claimed invention is highly unpredictable. Due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine

which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. In re Fisher, 427 F. 2d, 833, 166 USPQ 18 (CCPA 1970), indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, in the absence of a showing of treating all types of viruses, one of skill in the art is unable to fully predict possible results from the administration of the compounds found in Claims 1-4, due to the unpredictability of the art pertaining to many types of viral treatments, most notably HIV.

The amount of direction provided by the inventor

The instant specification is not seen to provide adequate guidance, which would allow the skilled artisan to extrapolate from the disclosure and examples provided, to use the claimed method commensurate in the scope with the instant claims. Applicant provides limited guidance regarding the use of the instant compound in treating all types of viruses. Applicant provides information on biological activity on page 20-24. The data and evidence provided in the instant disclosure leads the examiner to doubt the objective truth of assertions of treatment of all types of viruses.

The existence of working examples

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without

undue experimentation. In re Wright, 999 F. 2d 1557, 1562; 27 USPQ 2d 1510, 1514 (Fed. Cir. 1993). There is not seen in the disclosure, sufficient evidence to support applicant's claims of a method for the treatment of all types of viruses. Applicant provides biological examples on pages 20-24 of experiments with CMV. There is not seen sufficient working examples or data from references on the prior art providing a nexus between that which applicant asserts as proof of a method for treating all viruses.

The quantity of experimentation needed to make and use the invention based on the content of the disclosure

Based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation. It is suggested that applicant limit the methods of treating CMV, which is supported in the specification by biological data.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 contains the limitation that X can be nitrogen. However, if X is nitrogen alone, not NH for example, a valency problem exists.

2. Claim 2 contains the limitation that R_3 and R_4 can be OAc or OBn. However, there is insufficient antecedent basis for this limitation in the claim because claim1, from which claim 2

depends, does not contain OAc or Obn. Additionally, Claim 2 is indefinite because it contains a period in the middle of the claim (after the first OH functional group).

3. Claim 3 contains the limitation that R_1 and R_2 form a $OC(CH_3)_2O$- ring. However, there is insufficient antecedent basis for this limitation in the claim because claim1, from which claim 3 depends, does not contain this limitation. There is no indication in claim 1 that R_1 and R_2 can form a ring, including an acetal ring.

4. Claim 4 contains the limitation that R_3 and R_4 form a $-OSi(i\text{-}Pr)_2Osi(i\text{-}Pr)_2O$- ring. However, there is insufficient antecedent basis for this limitation in the claim because claim1, from which claim 4 depends, does not contain this limitation. There is no mention in claim 1 that R_3 or R_4 can contain a silicon moiety. Additionally, the ring formed by $-OSi(i\text{-}Pr)_2Osi(i\text{-}Pr)_2O$, is not an acetal ring, which is defined as a ring containing a carbon atom attached to two ether oxygens.

Claim Objections

Claim 8 is objected to for depending from a rejected base claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason H. Johnsen** whose telephone number is **571-272-3106**. The examiner can normally be reached on Mon-Friday, 8:30-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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